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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 10/706,547 | 11/12/2003 | Linda S. Powers | 13368.0001 (DIV. I) | 6904 |

7590 07/28/2004

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EXAMINER

YU, MELANIE J

| ART UNIT | PAPER NUMBER |
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1641

DATE MAILED: 07/28/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/706,547

Applicant(s)

POWERS ET AL.

Examiner

Melanie Yu

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 June 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 21-37 and 53 is/are pending in the application.
- 4a) Of the above claim(s) 24,25 and 27-37 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 21-23,26 and 53 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 12 November 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date <u>11/12/03</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

1. This application contains claims directed to the following patentably distinct species of the claimed invention:

Groups a-b each comprise a separate invention under 35 U.S.C. §121. These groups represent the identification method wherein the biological analyte to be identified is:

- a. proteinaceous toxins
- b. cytosolic proteins

Groups i-iii each comprise a separate invention under 35 U.S.C. §121. These groups represent the identification method wherein the ligand specific for the analyte of interest is:

- i. peptide specific to a proteinaceous toxin
- ii. peptide specific to a proteinaceous hormone
- iii. peptide specific to a cytosolic protein

Groups 1-7 each comprise a separate invention under 35 U.S.C. §121. These groups represent the identification method wherein the method of detection of the capture analyte is:

- (1) Through detecting the intrinsic fluorescence of the protein
- (2) Through fluorescence of a reactive dye conjugate
- (3) Through detecting the radioactivity of a reactive compound
- (4) Through luminescence of a reactive dye conjugate
- (5) Through phosphorescence of a reactive dye conjugate
- (6) Through optical absorbance of a reactive dye conjugate
- (7) Through fluorescent quenching of the tethered ligand surface.

1. The claims are deemed to correspond to the species listed above in the following manner:

The species for the biological analyte are drawn to claims 22.

The species for the ligand are drawn to the following claims: 23-25 and 53.

The species for the detection of the capture analyte are drawn to the following claims: 26-37.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species from each of the three groups listed above for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claim 21 is generic.

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Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

2. During a telephone conversation with Mr. K. Cornaby on 6/24/2004 a provisional election was made with traverse to prosecute the invention of Group(a) wherein the analyte is a proteinaceous toxin, Group(i) wherein the ligand is specific to a proteinaceous toxin, and Group(1) wherein the method of detection is through intrinsic fluorescence of the protein, claims 21-23, 26, and 53. Affirmation of this election must be made by applicant in replying to this Office action. Claims 24,25, and 27-37 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

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3. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Specification

4. The disclosure is objected to because of the following informalities: a spelling error on pg. 6: "thorough" should be --through--.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claim 26 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The claimed ligand that is a peptide not containing tryptophan or tyrosine, and the detection of such a ligand by intrinsic fluorescence is not disclosed in the specifications. It is noted that the detection of toxins containing tryptophan and tyrosine with tryptophan/tyrosine fluorescence after capture is disclosed in the specifications (pg. 14), but peptides not containing tryptophan or tyrosine are not disclosed.

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7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claims 21-23, 26, and 53 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

9. Claim 21, part (b) is vague and indefinite because it is unclear what type of physical separation is utilized. Part (c) is vague and indefinite because it is unclear how interrogation of the substrate surface is performed.

10. Claim 23, the term “usually” is vague and indefinite because it is a relative terminology. The length of the peptide is unclear because “usually” fails to define a precise range of peptide lengths.

11. Claim 26 is vague and indefinite because it is unclear how a peptide not containing tryptophan or tyrosine and the detection of such peptides are accomplished. It is noted that the detection of a toxin containing tryptophan and tyrosine is disclosed, but this does not provide sufficient disclosure for a peptide ligand not containing tryptophan or tyrosine.

12. Claim 53 is vague and indefinite because it is unclear whether the specific protein analyte of a proteinaceous toxin or cytosolic protein are part of the claimed invention. The limitation is recited in the preamble, and the body of the claim does not correlate the step of identifying the specific protein.

Claim Rejections - 35 USC § 102

13. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

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A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

14. Claims 21 and 53 are rejected under 35 U.S.C. 102(b) as being anticipated by Hudson et al. (U.S. patent 5,576,220). Hudson et al. teach a method for identification of a biological analyte comprising: exposing a solution containing the analyte (Fig. 1, label “TTM”; col. 3, lines 64-67; col. 4, lines 1-5) to a ligand specific for the analyte of interest (Fig. 1, label “L”; col. 3, lines 64-67; col. 4 lines 1-5) that has been covalently tethered (Fig. 1, labels “T”, “4”, and “6”; col. 5, lines 37-39; col. 4, lines 48-52; col. 14, lines 11-14) to a substrate surface with a photostable linker (Fig. 1, labels “3”, “10”, “11”, “12”, and “T”; col. 8, lines 12-24) at a distance of 15-50 Å, which would encompass the recited “at least six Å” (Fig. 1, label “A”; col. 7, lines 48-50) for the capture of proteins (col. 1, lines 27-36; col. 3, lines 14-16); separating the bound analyte from the non-binding components of the solution containing the analyte by physical separation, washing or both (col. 14, lines 36-38; col. 18, lines 5-9); and interrogation of the ligand-tethered substrate surface for analyte binding (col. 1, lines 36-48; col. 3, lines 56-58; col. 14, lines 36-38). Hudson et al. also teach a peptide ligand containing three to twenty amino acids (col. 7, lines 64-67; col. 8, lines 1-11).

15. With respect to claim 53, the specific protein is not given patentable weight since it is recited in the preamble and the body of the claim does not correlate the step of identifying the specific protein.

Claim Rejections - 35 USC § 103

16. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The inquiries for establishing whether an invention is obvious over the prior art in accordance with *Graham v. John Deere*, 383 U.S. 1,148 USPQ 459 (1966) can be summarized as follows:

1. Determine the scope of the claimed invention
2. Determine the scope and content of the prior art.
3. Determine if there are any differences between the claimed invention and the prior art.
4. Determine if any differences are such that the invention would have been obvious to one of ordinary skill in the art.

17. Claims 22, 23, and 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hudson et al. in view of Powers et al. (PCT publication WO 98/49557).

18. Hudson et al. teach the method of identification of a biological analyte including a peptide ligand containing three to twenty amino acids, as discussed above. Hudson et al., however, do not teach a biological analyte being a proteinaceous toxin, a ligand specific for a proteinaceous toxin, detection of captured analyte through intrinsic fluorescence of the protein, or the identification of a protein analyte wherein the protein is a proteinaceous toxin.

Powers et al. teach a method for taxonomic identification of microorganisms wherein the analyte is a proteinaceous toxin (pg.1, 1st paragraph and pg. 10, 2nd paragraph) and a ligand specific to the toxin (pgs. 13-14), in order to capture and detect a specific proteinaceous toxin, which are potential infections.

Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to include in the method of Hudson et al., a proteinaceous toxin and a

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ligand specific to the toxin, as taught by Powers et al., in order to detect and identify proteinaceous toxins within a sample, since these toxins are known as potential infections and also of concern to vertebrate animals including humans, livestock, poultry, and wildlife.

19. Intrinsic fluorescence, recited in claim number 26, is taught by Powers et al. (pg. 18, 1st paragraph; pg. 32, 1st paragraph).

Conclusion

20. No claims are allowed.

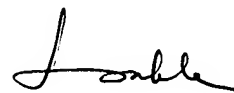
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Melanie Yu whose telephone number is (571) 272-2933. The examiner can normally be reached on M-F 8:30-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on (571)272-0823. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Melanie Yu
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7/26/04



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